

FORM PTO-1390
(REV. 1-98)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

0020-4802P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

09/743750

INTERNATIONAL APPLICATION NO.

PCT/JP99/03837

INTERNATIONAL FILING DATE

16 JULY 1999

PRIORITY DATE CLAIMED

16 JULY 1998

TITLE OF INVENTION

FORMULATIONS USEFUL FOR IMMUNOTHERAPY FOR CANCERS CONTAINING BACTERIAL COMPONENT AS AN
ACTIVE INGREDIENT

APPLICANT(S) FOR DO/EO/US

AZUMA, Ichiro; HAMAMATSU, Norio; FUJINAGA, Toshio

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau. WO00/03724
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(3)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98./International Search Report
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
FORM PCT/IPEA/409 - INTERNATIONAL PRELIMINARY EXAMINATION REPORT
ENGLISH TRANSLATION OF ARTICLE 34 CLAIMS
EIGHT (8) SHEETS OF FORMAL DRAWINGS

500 PCT/PTO 1 6 JAN 2001

U.S. APPLICATION NO. (2001) 09/743750 NEW		INTERNATIONAL APPLICATION NO. PCT/JP99/03837		ATTORNEY'S DOCKET NUMBER 0020-4802P	
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<p>17. <input checked="" type="checkbox"/> The following fees are submitted:</p> <p>BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1,000.00</p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00</p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO. \$710.00</p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00</p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00</p> <p>ENTER APPROPRIATE BASIC FEE AMOUNT =</p> <p>Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:20%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:20%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> <th style="width:20%;"></th> <th style="width:20%;"></th> </tr> <tr> <td>Total Claims</td> <td>27 - 20 =</td> <td>7</td> <td>X \$18.00</td> <td>\$</td> <td>126.00</td> </tr> <tr> <td>Independent Claims</td> <td>6 - 3 =</td> <td>3</td> <td>X \$80.00</td> <td>\$</td> <td>240.00</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable) YES</td> <td>+ \$270.00</td> <td>\$</td> <td>270.00</td> </tr> <tr> <td colspan="4" style="text-align: right;">TOTAL OF ABOVE CALCULATIONS =</td> <td>\$</td> <td>1,626.00</td> </tr> <tr> <td colspan="4">Reduction of 1/2 for filing by small entity, if applicable.</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4">Applicant claims Small Entity Status in accordance with 37 CFR 1.27.</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;">SUBTOTAL =</td> <td>\$</td> <td>1,626.00</td> </tr> <tr> <td colspan="4">Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;">TOTAL NATIONAL FEE =</td> <td>\$</td> <td>1,626.00</td> </tr> <tr> <td colspan="4">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;">TOTAL FEES ENCLOSED =</td> <td>\$</td> <td>1,626.00</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: right;">Amount to be:</td> <td>\$</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: right;">refunded</td> <td>\$</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: right;">charged</td> <td>\$</td> </tr> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			Total Claims	27 - 20 =	7	X \$18.00	\$	126.00	Independent Claims	6 - 3 =	3	X \$80.00	\$	240.00	MULTIPLE DEPENDENT CLAIM(S) (if applicable) YES			+ \$270.00	\$	270.00	TOTAL OF ABOVE CALCULATIONS =				\$	1,626.00	Reduction of 1/2 for filing by small entity, if applicable.				\$		Applicant claims Small Entity Status in accordance with 37 CFR 1.27.				\$		SUBTOTAL =				\$	1,626.00	Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$		TOTAL NATIONAL FEE =				\$	1,626.00	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$		TOTAL FEES ENCLOSED =				\$	1,626.00					Amount to be:	\$					refunded	\$					charged	\$	<p>CALCULATIONS</p> <p>PTO USE ONLY</p>
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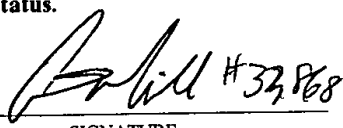
a. ☒ A check in the amount of \$ 1,626.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of \$ _____ to cover the above fees.
 A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
 overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to:
Birch, Stewart, Kolasch & Birch, LLP or Customer No. 2292
P.O. Box 747
Falls Church, VA 22040-0747
(703)205-8000


 SIGNATURE
BAILEY, JOHN W.
 NAME
#32,881 (JWB)
 REGISTRATION NO.

/gf January 16, 2001

(REV. 12/11/2000)

**Amendment under Article 11 of the Law Concerning
International Application under PCT**

1. International Application Number

PCT/JP99/03837

2. Applicant

Name: AZUMA Ichiro

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3. Patent Attorney

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Shiromi 1-chome, Chuo-ku, Osaka-shi, OSAKA 540-0001

JAPAN

4. Date of Notification

22.02.00

5. Object to be amended

Claims

6. Content of amendment

As shown in the attached sheet, a stabilizer is restricted to an amino acid or urea in independent claims of claims 1 and 6, whereas a bacterial component is restricted to a BCG-CWS and *Nocardia rubra* CWS, and step (b) is amended in an independent claim of claim 11. In claims 5 and 10, a stabilizer is amended to an amino acid. Claims 4, 9, and 12 are deleted, and, in the dependent claims from these claims, claim numbers showing these claims are amended. Claims 21 to 25 are added.

7. Appendix

Amended page-45, 46, 47, 48-1 and 48-2 of the claims are herein attached.